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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/361,576	07/27/99	STOCKWELL B	2001180-0028

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1627	4

DATE MAILED: 02/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/361,576	Stockwell et al.
Examiner	**Group Art Unit**
Grace Hsu, Ph.D.	1627

☒ Responsive to communication(s) filed on *Jan 19, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-38* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-38* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Please Note: *In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is* ***(703) 305-3704****. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.*

1. The Petition of Extension of Time, Declaration and Fees filed January 19, 2000 was received and entered as Paper No. 3.

2. Claims 1-38 are currently pending.

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to a method for screening chemical compounds, classified in class 436, subclass 518 and in class 435, subclass 4.

II. Claims 26-33, systems for identifying compounds capable of affecting a biological or chemical process, classified in class 435, subclass 7.1 and in class 436, subclass 518.

III. Claim 34, drawn to a composition comprising one or more compounds depicted in Figure 16 and claim 36 drawn to a composition of claim 34, further comprising a pharmaceutically acceptable carrier, classified in class 546, subclass 159.

IV. Claim 35, drawn to a composition comprising one or more compounds depicted in Figure 17 and claim 36 drawn to a composition of claim 35, further comprising a pharmaceutically acceptable carrier, classified in class 564, subclass 251.

V. Claim 37, drawn to a method of stimulating expression of TGFβy-responsive genes, classified in class 435, subclass 4.

VI. Claims 74-79, drawn to a method of altering metal concentration in a system, classified in class 435, subclass 7.1.

4. The inventions are distinct, each from the other, because of the following reasons:

5. Groups I, V and Group VI represent separate and distinct inventions. Groups I, V and VI are drawn to different methods (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product or lead to different final results). Therefore, Groups I, V and Group VI have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

6. Groups I, V and VI and Groups III and IV represent separate and distinct inventions. Group I, V and VI are different from Groups III and IV in that Groups I, V and VI are drawn to different methods (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product or lead to different final results), while Groups III and IV are drawn to different compositions (each comprised of a different composition or a collection of compounds, which have biological, therapeutic or some other functional uses).. Therefore, Groups I, V and VI and Groups III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

7. Group II and Groups I, V and Group VI represent separate and distinct inventions. Group II is different from Groups I, V and VI in that Group II is drawn to a systems for

identifying compounds capable of affecting a biological or chemical process (which represents an apparatus, which are defined as machines and devices, having cooperative parts that accomplish some useful result, act or operation on itself or on an article or workpiece), while Groups I, V and VI are drawn to different methods (which are directed to different purposes, use different materials, recite different method steps for the preparation of different product or lead to different final results). Therefore, Groups II and Groups I, V and VI have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

8. Group II and Groups III and IV represent separate and distinct inventions. Group II is different from Groups III and IV in that Group II is drawn to a systems for identifying compounds capable of affecting a biological or chemical process (which represents an apparatus, which are defined as machines and devices, having cooperative parts that accomplish some useful result, act or operation on itself or on an article or workpiece), while Groups III and IV are drawn to different compositions (each comprised of a different composition or a collection of compounds, which have biological, therapeutic or some other functional uses).. Therefore, Groups II and Groups III and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

9. Groups III and Group IV represent separate and distinct inventions. Groups III and IV are drawn to different compositions (each comprised of a different composition or a collection of compounds, which have biological, therapeutic or some other functional uses). Therefore, Group

II and Group IV have different issues regarding patentability and enablement and represent patentably distinct subject matter, which merits separate and burdensome searches.

10. These inventions are distinct for the reasons above and have acquired a separate status in the art because of their recognized divergent subject matter and/or shown by their different classifications. While some of the aforementioned groups are classified under an identical class/sub-class, the corresponding non-patent literature search remains unaffected. Each of the identified groups may require different searches. For example, methods and products groups require different searches. Therefore, restriction for examination purposes as indicated is proper.

11. This application contains claims directed to the following patentably distinct species of the claimed invention.

12. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species A** of the claimed invention:

Species A	**claim no.**	**The method of claim 1, wherein the step of providing an assay format comprises:**
(1)	claim 2	providing an assay format containing a plurality of reaction vessels arranged with sufficient density that individual vessels are separated from one another by no more than about 2 millimeters
(2)	claim 3	providing an assay format containing a plurality of reaction vessels arranged with sufficient density that individual vessels are separated from one another by no more than about 1 millimeters

(3)	claim 4	providing an assay format containing a plurality of reaction vessels arranged with sufficient density that individual vessels are separated from one another by no more than about 0.25 millimeters

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

13. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species B** of the claimed invention:

Species B	**claim no.**	**The method of claim 5, wherein the step of introducing at least one cell comprises:**
(6)	claim 6	introducing at least one eukaryotic cell
(7)	claim 7	introducing at least one mammalian cell
(8)	claim 8	introducing at least one human cell

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

14. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species C** of the claimed invention:

Species C	**claim no.**	**The method of claim 1, wherein the step of detecting comprises:**
(9)	claim 10	detecting an intracellular event or entity
(10)	claim 11	detecting a luminescent moiety
(11)	claim 12	detecting a chemiluminescent moiety generated by a peroxidase, and utilizes at least one antibody to bind a biological component

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

15. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species D** of the claimed invention:

Species D	**claim no.**	**The method of claim 13, wherein the step of providing an assay format comprises:**
(12)	claim 14	providing an assay format containing at least 100 reaction vessels, wherein a volume of each reaction vessel is less than or equal to approximately 200 microliters
(13)	claim 15	providing an assay format containing at least 300 reaction vessels, wherein a volume of each reaction vessel is less than or equal to approximately 50 microliters
(14)	claim 16	providing an assay format containing at least 1000 reaction vessels, wherein a volume of each reaction vessel is less than or equal to approximately 2 microliters
(15)	claim 17	providing an assay format containing at least 5000 reaction vessels, wherein a volume of each reaction vessel is less than or equal to approximately 250 nanoliters

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

16. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species F** of the claimed invention:

Species F	**claim no.**	**The method of claim 18, wherein the step of introducing at least one cell:**
(16)	claim 19	introducing at least one eukaryotic cell
(17)	claim 20	introducing at least one mammalian cell
(18)	claim 21	introducing at least one human cell

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 is generic.

17. If applicants elect the invention of **Group I**, applicants are required to further elect from the following patentably distinct **Species G** of the claimed invention:

Species G	**claim no.**	**The method of claim 2, wherein the step of detecting comprises:**
(19)	claim 23	detecting an intracellular event or entity
(21)	claim 24	detecting a chemiluminescent moiety
(22)	claim 25	detecting a chemiluminescent moiety generated by a peroxidase, and wherein the step of detecting utilizes at least one antibody to bind a biological component

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

18. If applicants elect the invention of **Group II**, applicants are required to further elect from the following patentably distinct **Species H** of the claimed invention:

Species H	**claim no.**	**The system of claim 26, wherein the array of reaction vessels contains at least:**
(23)	claim 27	300 reaction vessels, wherein each vessel has a volume less than or equal to approximately 50 microliters
(24)	claim 28	1000 reaction vessels, wherein each vessel has a volume less than or equal to approximately 2 microliters
(25)	claim 29	5000 reaction vessels, wherein each vessel has a volume less than or equal to approximately 250 microliters

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 26 is generic.

19. If applicants elect the invention of **Group II**, applicants are required to further elect from the following patentably distinct **Species I** of the claimed invention:

Species I	**claim no.**	**The system of claim 30, wherein the array of reaction vessels contains at least:**
(23)	claim 31	300 reaction vessels, wherein each vessel has a volume less than or equal to approximately 50 microliters, wherein the assay solution detects levels of a component in a biological or a chemical process or resulting from a biological or a chemical process by using chemiluminescence and wherein compounds for screening are synthesis by combinatorial chemistry
(24)	claim 32	1000 reaction vessels, wherein each vessel has a volume less than or equal to approximately 2 microliters, wherein the assay solution detects levels of a component in a biological or a chemical process or resulting from a biological or a chemical process by using chemiluminescent compounds generated by a peroxidase and wherein compounds for screening are synthesis by combinatorial chemistry
(25)	claim 33	5000 reaction vessels, wherein each vessel has a volume less than or equal to approximately 250 microliters, wherein the assay solution detects levels of a component in a biological or a chemical process or resulting from a biological or a chemical process by using chemiluminescent compounds generated by horseradish peroxidase and wherein compounds for screening are synthesis by combinatorial chemistry

Each of the species identified above represents patentably distinct subject matter. In the instant case, those species each involve different structures and modes of action. Therefore, those species involve different patentability and enablement issues.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 30 is generic.

20. Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

21. Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

22. Should applicants traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

23. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

24. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Conclusion

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Grace C. Hsu, Ph.D., J.D. whose telephone number is (703) 308-7005. The Examiner may be reached during normal business hours, Monday through Friday from 8:30 am to 6:00 pm (EST). A message may be left on the Examiner's voice mail.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Donald E. Adams, Ph.D., J.D. may be reached at (703) 308-0570. The fax number assigned to Group 1627 is (703) 305-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1627 receptionist whose telephone number is (703) 308-0196.

Grace C. Hsu, Ph.D.
February 26, 2000

BENNETT CELSA
PRIMARY EXAMINER

2/27/00